

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

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Application of: Thomas, Lawrence J.  
Serial No.: 09/845,511  
Filed: April 30, 2001  
Entitled: PLASMID-BASED VACCINE FOR  
TREATING ATHEROSCLEROSIS

Examiner: Nguyen, Dave T.

Art Unit: 1632

**Continuation of U.S. Appln. Ser. No. 09/171,969**

Attorney Docket No.: TCS-414.2P US-1

Commissioner for Patents  
P.O. Box 1450  
Alexandria, VA 22313-1450

**RESUBMISSION OF  
INFORMATION DISCLOSURE STATEMENT  
UNDER 37 C.F.R. §§ 1.56, 1.97 AND 1.98**

Dear Sir:

In accordance with the duty of disclosure under 37 C.F.R. § 1.56, Applicants submit this Information Disclosure Statement pursuant to 37 C.F.R. §§ 1.97 and 1.98 in the above-identified application for consideration by the Patent Office. A listing of the cited documents is also enclosed, as well as, for the Examiner's convenience, copies of the documents in the list. **This Statement was previously submitted before the first Office Action on the merits pursuant to 37 C.F.R. § 1.97(b)(3). A copy of that prior submission is attached (Tab A) along with a copy of the return receipt postcard (Tab B). Accordingly, Applicants believe that no fee is required for this submission.**

**US Patents**

US 5,242,687; issued September 7, 1993, Tykocinski et al.;

US 5,338,829; issued August 16, 1994, Weiner et al.; and

US 5,705,388; issued January 6, 1998, Couture et al.

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WO 90 15627 published December 27, 1990, Arlinghaus et al.;

WO 92 10203 published June 25, 1992, Swartz;

WO 93 11782 published June 24, 1993, Kushwaha et al.;

WO 93 23076 published November 25, 1993, Cheronis;

WO 94 24567 published October 27, 1994, Brocia et al.;

WO 94 25060 published November 10, 1994, Ladd et al.; and

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Yen et al., *J. Clin. Invest.*, 83: 2018-2024 (1989);

Zannis et al., "Genetic mutations affecting human lipoproteins, their receptors, and their enzymes". In Advances in Human Genetics, Vol. 21, pp. 145-319 (Plenum Press, New York, 1993);

Zegers et al., *Eur. J. Immunol.*, 23: 630-634 (1993); and

Zhang et al., *Cell*, 1: 751-761 (1994).

Applicants do not intend to represent that any of the documents submitted herein is material prior art to this invention or that the list represents an exhaustive search of documents related to this invention.

Applicants respectfully request that the documents submitted herein be considered and made of record in this application.

Respectfully submitted,



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Leon R. Yankwich, Esq., Reg. No. 30,237  
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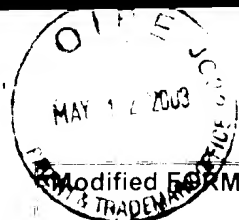
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Michael R. Wesolowski



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LIST OF PATENTS AND PUBLICATIONS FOR APPLICANT'S INFORMATION DISCLOSURE STATEMENT		APPLICANT Thomas, Lawrence J.	
(Use several sheets if necessary)		FILING DATE April 30, 2001	GROUP 1632

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REFERENCE DESIGNATION

U.S. PATENT DOCUMENTS

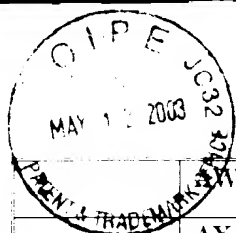
EXAMINER INITIAL		DOCUMENT NUMBER	DATE	NAME	CLASS	SUBCLASS	FILING DATE IF APPROPRIATE
	AA	US 5,242,687	09/07/93	Tykocinski et al.			
	AB	US 5,338,829	08/16/94	Weiner et al.			
	AC	US 5,705,388	01/06/98	Couture et al.			

FOREIGN PATENT DOCUMENTS

		DOCUMENT NUMBER	DATE	NAME	CLASS	SUBCLASS	TRANSLATION YES NO	
	AD	EP 0343460 A2	11/29/89	Sinigaglia				
	AE	WO 90/15627	12/27/90	Arlinghaus et al.				
	AF	WO 92/10203	06/25/92	Swartz et al.				
	AG	WO 93/11782	06/24/93	Kushwaha et al.				
	AH	WO 93/23076	11/25/93	Cheronis				
	AI	WO 94/24567	10/27/94	Brocia et al.				
	AJ	WO 94/25060	11/10/94	Ladd et al.				
	AK	WO 96/39168	12/12/96	Kwoh et al.				

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	AL	Ada, G.L., Fundamental Immunology, 3rd ed., pp. 1309 - 1352 (W. E. Paul, ed.) (Raven Press, Ltd., New York, 1993)
	AM	Agellon, L.B. et al., <i>J. Biol. Chem.</i> , 266: 10796 - 10801 (1991)
	AN	Aitken, R.J. et al., <i>Brit. Med. Bull.</i> , 49: 88 - 99 (1993)
	AO	Albers et al., <i>Arteriosclerosis</i> , 4: 49-58 (1984)
	AP	Alexander et al., <i>Immunity</i> , 1: 751-761 (1994)
	AQ	Barter et al., <i>J. Lipid Res.</i> , 21: 238-249 (1980)
	AR	Bevilacqua et al., <i>J. Clin. Invest.</i> , 91: 379-387 (1993)
	AS	Bisgaier et al., <i>J. Lipid Res.</i> , 32: 21-23 (1991)
	AT	Bisgaier et al., <i>J. Lipid Res.</i> , 34: 1625-1634 (1993)
	AU	Breslow et al., <i>Proc. Natl. Acad. Sci. USA</i> , 90: 8314-8318 (1993)
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		Carlsson et al., <i>Biochem. J.</i> , 173: 723-737 (1978)
	AX	Casali et al., <i>Science</i> , 234: 476-479 (1986)
	AY	Castelli et al., <i>J. Am. Med. Assoc.</i> , 256: 2835-2838 (1986)
	AZ	<u>Current Protocols in Immunology</u> , pp. 3.11.1 - 3.11.15, 3.12.1 - 3.12.14 (Coligan, J.E. et al., eds.) (John Wiley & Sons, New York, 1994);
	BA	Drayna et al., <i>Nature</i> , 327: 632-634 (1987)
	BB	Eldridge et al., in <u>Immunobiology of Proteins and Peptides V: Vaccines: Mechanisms, Design, and Applications</u> , Atassi, M.Z., ed. (Plenum Press, New York, 1989), pp. 191-202
	BC	Engelhard, Victor H., <i>Sci. Am.</i> , 54-60 (1994)
	BD	Etlinger et al., <i>Science</i> , 249: 423-425 (1990)
	BE	Etlinger, H., <i>Immunol. Today</i> , 13: 52-55 (1992)
	BF	Farmer, J.A. et al., <u>Heart Disease. A Textbook of Cardiovascular Medicine</u> , 4th ed., pp. 1125 - 1160 (Braunwald, E., ed.) (W. B. Saunders Co., Philadelphia, 1992)
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	BH	Gavish et al., <i>J. Lipid Res.</i> , 28: 257-267 (1987)
	BI	Gaynor et al., <i>Atherosclerosis</i> , 110: 101-109 (1994)
	BJ	<i>Genetic Engineering News</i> , 14: 44 (August 1994)
	BK	Gordon et al., <i>N. Engl. J. Med.</i> , 321: 1311-1316 (1989)
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	BP	Havel et al., "Introduction: Structure and metabolism of plasma lipoproteins". In <u>The Metabolic Basis of Inherited Disease</u> , 6th ed., pp. 1129-1138 (Scriver, et al., eds.) (McGraw-Hill, Inc., New York, 1989)
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	BY	Jiang et al., <i>J. Biol. Chem.</i> , 268: 27406-27412 (1993)

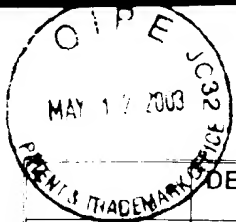


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CF	Mader, S.S., In <i>Human Biology</i> , 4th ed., pp. 83, 102 (Wm. C. Brown Publishers, Dubuque, Iowa, 1995)
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CI	Mathews, C.K. and van Holde, K.E., <i>Biochemistry</i> , pp. 574-576, 626-630 (The Benjamin/Cummings Publishing Co., Redwood City, California, 1990)
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CQ	Pruitt et al., <i>J. Surg. Res.</i> , 50: 350-355 (1991)
CR	Pruitt et al., <i>Transplantation</i> , 52: 868-873 (1991)
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CV	Rosen et al., <i>J. Immunol. Methods</i> , 172: 135-137 (1994)
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DB	Swenson et al., <i>J. Biol. Chem.</i> , 264: 14318-14326 (1989)
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DE	Tall, A.R., <i>J. Internal Med.</i> , 237: 5-12 (1995)
DF	Talwar et al., <i>Proc. Natl. Acad. Sci. USA</i> , 91: 8532-8536 (1994)
DG	Tam, J.P., <i>Proc. Natl. Acad. Sci. USA</i> , 85: 5409-5413 (1988)
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DK	Travis, <i>Science</i> , 262: 1974-1975 (1993)
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DZ	Zhang et al., <i>Cell</i> , 1: 751-761 (1994)

EXAMINER

DATE CONSIDERED

**EXAMINER:** Initial if reference considered, whether or not citation is in conformance with MPEP §609. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to Applicant.

sheet 4 of 4

TAB A



IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

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MAY 1 2003  
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Inventor of: Thomas, Lawrence J.

Serial No.: 09/845,511

Filed: April 30, 2001

Entitled PLASMID-BASED VACCINE FOR  
TREATING ATHEROSCLEROSIS

Examiner: not yet assigned

Art Unit: 1614

Attorney Docket No.: TCS-414.2P US-1

Assistant Commissioner for Patents  
Washington, D.C. 20231

**INFORMATION DISCLOSURE STATEMENT  
UNDER 37 C.F.R. §§ 1.56, 1.97 AND 1.98**

Dear Sir:

In accordance with the duty of disclosure under 37 C.F.R. § 1.56, Applicants submit this Information Disclosure Statement pursuant to 37 C.F.R. §§ 1.97 and 1.98 in the above-identified application for consideration by the Patent Office. A listing of the cited documents is also enclosed, as well as, for the Examiner's convenience, copies of the documents in the list. Pursuant to 37 C.F.R. § 1.97(b)(3), because this Statement is being submitted before the first Office Action on the merits, no fee is required.

**US Patents**

US 5,242,687; issue date 07 September 1993; Tykocinski et al.  
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US 5,705,388; issue date 06 January 1998; Couture et al.

**Foreign Patent Applications**

EPO, Publication No. EP 0343460 A2. Publication Date 29 November 1989.  
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PCT, Publication No. WO 93/11782. Publication Date 24 June 1993.  
PCT, Publication No. WO 93/23076. Publication Date 25 November 1993.  
PCT, Publication No. WO 94/24567. Publication Date 27 October 1994.  
PCT, Publication No. WO 94/25060. Publication Date 10 November 1994.  
PCT, Publication No. WO 96/39168. Publication Date 12 December 1996.

**Other Publications**

Ada, G.L., Fundamental Immunology, 3rd ed., pp. 1309 - 1352 (W. E. Paul, ed.) (Raven Press, Ltd., New York, 1993).

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Zhang et al., *Cell*, 1: 751-761 (1994).

Applicants do not intend to represent that any of the documents submitted herein is material prior art to this invention or that the list represents an exhaustive search of documents related to this invention.

Applicants respectfully request that the documents submitted herein be considered and made of record in this application.

Respectfully submitted,



Leon R. Yankwich; Reg. No. 30,237

Thomas R. Berka, Ph.D.

Attorney(s) for Applicants

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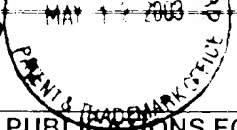
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Modified FORM PTO-1449  LIST OF PATENTS AND PUBLICATIONS FOR APPLICANT'S INFORMATION DISCLOSURE STATEMENT  (Use several sheets if necessary)	<table border="1" style="width: 100%; border-collapse: collapse;"> <tr> <td style="width: 50%;">ATTY. DOCKET NO.</td> <td style="width: 50%;">SERIAL NO.</td> </tr> <tr> <td>TCS-414.2P US-1</td> <td>09/845.511</td> </tr> <tr> <td colspan="2">APPLICANT</td> </tr> <tr> <td colspan="2">Thomas, Lawrence J.</td> </tr> <tr> <td>FILING DATE</td> <td>GROUP</td> </tr> <tr> <td>April 30, 2001</td> <td>(not yet assigned)</td> </tr> </table>	ATTY. DOCKET NO.	SERIAL NO.	TCS-414.2P US-1	09/845.511	APPLICANT		Thomas, Lawrence J.		FILING DATE	GROUP	April 30, 2001	(not yet assigned)
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APPLICANT													
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FILING DATE	GROUP												
April 30, 2001	(not yet assigned)												

**REFERENCE DESIGNATION**
**U.S. PATENT DOCUMENTS**

EXAMINER INITIAL	DOCUMENT NUMBER	DATE	NAME	CLASS	SUBCLASS	FILING DATE IF APPROPRIATE
AA	US 5,242,687	09/07/93	Tykocinski et al.			
AB	US 5,338,829	08/16/94	Weiner et al.			
AC	US 5,705,388	01/06/98	Couture et al.			

**FOREIGN PATENT DOCUMENTS**

DOCUMENT NUMBER	DATE	NAME	CLASS	SUBCLASS	TRANSLATION YES NO
AD EP 0 343 460 A2	11/29/89		C07K	7/08	
AE WO 90/15627	12/27/90		A61K	47/48	
AF WO 92/10203	06/25/92		A61K	37/22	
AG WO 93/11782	06/24/93		A61K	37/00	
AH WO 93/23076	11/25/93		A61K	39/00	
AI WO 94/24567	10/27/94		G01N	33/92	
AJ WO 94/25060	11/10/94		A61K	37/38	
AK WO 96/39168	12/12/96		A61K	38/17	

**OTHER ART (Including Author, Title, Date, Pertinent Pages, Etc.)**

AL	Ada, <u>Fundamental Immunology</u> , 3rd ed., pp. 1309 - 1352 (W. E. Paul, ed.) (Raven Press, Ltd., New York, 1993)
AM	Agellon et al., <i>J. Biol. Chem.</i> , 266: 10796 - 10801 (1991)
AN	Aitken et al., <i>Brit. Med. Bull.</i> , 49: 88 - 99 (1993)
AO	Albers et al., <i>Arteriosclerosis</i> , 4: 49-58 (1984)
AP	Alexander et al., <i>Immunity</i> , 1: 751-761 (1994)
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OTHER DOCUMENTS (Including Author, Title, Date, Pertinent Pages, Etc).

AQ	Barter et al., <i>J. Lipid Res.</i> , 21:238-249 (1980)
AR	Bevilacqua et al., <i>J. Clin. Invest.</i> , 91: 379-387 (1993)
AS	Bisgaier et al., <i>J. Lipid Res.</i> , 34: 1625-1634 (1991)
AT	Bisgaier et al., <i>J. Lipid Res.</i> , 32: 21-23 (1993)
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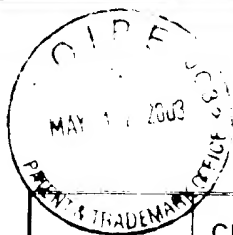
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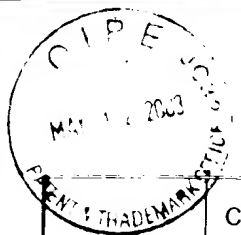


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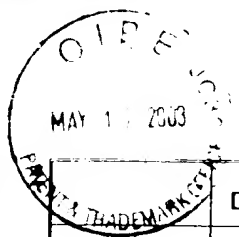
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	DA	Roy, et al., <i>J. Lipid Res.</i> , 37: 22 - 34 (1996)
	DB	Rye et al., <i>J. Biol. Chem.</i> , 270: 189-196 (1995)
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	DO	<u>The Merck Manual of Diagnosis and Therapy</u> , 16 <sup>th</sup> ed., (Merck & Company Inc., Rahway, New Jersey, 1992), pp. 22-23 (referring to infection prevention), pp. 114-115 (referring to bacterial diseases), pp. 1944-1947 (referring to health management of neonates, infants, and children).
	DP	Travis, <i>Science</i> , 262: 1974-1975 (1993)
	DQ	Valmori et al., <i>J. Immunol.</i> , 149: 717-721 (1992)
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DT	Wang et al., <i>J. Biol. Chem.</i> , 268: 1955-1959 (1993)
DU	Wang et al., <i>J. Biol. Chem.</i> , 267: 17487-17490 (1992)
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TAB B

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Serial No. 09 845,511 filed April 30, 2001  
Applicants: Thomas

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